Section 2 - Summary & Certification

2.1 510(k) Summary

A 510(k) Summary of Safety and Effectiveness is on the next page.

K953904

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K953904

August 9, 1995

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K953904.

This 510(k) is for the *Sarns 9000 Universal Roller Pump*, a "Roller-type cardiopulmonary bypass blood pump" and "Cardiopulmonary bypass pump speed control". The new *Sarns 9000 Universal Roller Pump* is substantially equivalent to the existing *Sarns 9000 Universal Roller Pump* (K871131).

The *Sarns 9000 Universal Roller Pump* is a microprocessor controlled 2-roller peristaltic pump with adjustable occlusion. The pump is capable of flows up to 9.99 L/min (depending on pump head tubing used) at pump speeds up to 250 RPM. The *Sarns 9000 Universal Roller Pump* is dependent on the *Sarns 9000 Perfusion System* to provide power.

The *Sarns 9000 Universal Roller Pump* is indicated for use in extracorporeal circulation of blood for arterial regional perfusion, and cardiopulmonary bypass procedures only, when used by a qualified perfusionist who is experienced in the operation of Sarns or similar equipment.

The *Sarns 9000 Universal Roller Pump* has different technological characteristics from the predicate device. The design and the manufacturing process have been changed. The modified roller pump is manufactured using some Surface Mount Technology (SMT) components and processes to produce the circuit boards which contain the pump electronics. The electronic packaging of some of the components on these circuit boards is SMT instead of Through-Hole Technology (THT). Also, the software has undergone minor changes to remap the I/O addresses.

The *Sarns 9000 Universal Roller Pump* has the same performance as the predicate device. Nonclinical tests were performed on the device to determine substantial equivalence. Electromagnetic Compatibility (EMC) tests were also performed to ensure equivalent or better results.

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2.2 Safety Literature Search

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for blood roller pumps. I further certify that I am aware of the types of problems to which blood roller pumps are susceptible and that the following list of safety and/or effectiveness problems about blood roller pumps is complete and accurate:

1.) Air Emboli
2.) Hemolysis
3.) Loss of speed control
4.) Random pump stops

Below is a bibliography of the materials upon which the above summary is based:

1.) Customer Field Input Log, various dates, Sarns, 3M Health Care
2.) Intermittent Failure of a Stockert/Shiley Multiflow Roller Pump Module, The Journal of Extra-Corporeal Technology, Volume 25, Number 3, 1993
3.) Medical Device Report M566956, M186992, M186044, M138277, various dates, Sarns, 3M Health Care
4.) Medical Device Report M494536, filed 4/21/94, Sarns, 3M Health Care
5.) Medical Device Report M444060, M123912, M111730, M101274, various dates, Sarns, 3M Health Care
6.) Medical Device Report M435457, M242746, M225052, M184140, M138914, M174191, various dates, Sarns, 3M Health Care
7.) Medical Device Report M377761, filed 2/26/93, Sarns, 3M Health Care
8.) Medical Device Report M125141, received 6/24/86, Cobe Labs, Inc.
9.) Medical Device Report M269021, M244886, M244883, M225527, M210562, M210551, M210545, M129763, various dates, Shiley, Inc.
10.) Medical Device Report M266724, M245762, M243742, M221182, various dates, Shiley, Inc.
11.) Medical Device Report M253241, M250682, M225194, M221859, various dates, Shiley, Inc.
12.) Medical Device Report M235614, M233235, various dates, Shiley, Inc.
13.) Medical Device Report M220822, M212362, M212346, M210217, M166630, M164988, M137248, various dates, Shiley, Inc.
14.) Medical Device Report M210544, received 8/17/90, Shiley, Inc.
15.) Medical Device Report M218408, received 12/10/90, Shiley, Inc.
16.) Medical Device Report M218946, received 12/17/90, Shiley, Inc.
17.) Medical Device Report M162834, received 1/5/89, Shiley, Inc.
18.) Medical Device Report M162828, M162829, M162830, M162831, M162832, M162833, M162836, M162838, M162839, M162840, M162841, M164234, M164858, M164860, M164850, M164934, M169675, various dates, Shiley, Inc.
19.) Medical Device Report M151200, received 2/26/88, Shiley, Inc.
20.) Medical Device Report M113582, received 11/5/92, Shiley, Inc.

Bibliography (continued)

21.) Medical Device Report M149951, M154495, M158908, M162835, M162837, M166744, M169035, M181659, M183581, M183582, M201061, M203578, M204035, M204038, M204528, M206003, M206119, M206314, M206208, M209511, M214496, M218406, M218555, M218949, M218952, M218954, M220245, M220248, M220824, M221189, M221190, M222866, M225528, M225533, M232442, M231336, M231337, M231338, M235611, M235947, M238231, M248275, M243327, M244887, M245205, M245936, M245940, M247740, M247741, M249816, M249823, M252531, M262466, M268638, M269022, M269713, M272031, various dates, Shiley, Inc.

22.) Medical Device Report M364517, M311533, M310489, M308281, M306710, M306708, M306205, M283826, M282507, M273690, various dates, Sorin Biomedical, Inc.

23.) Medical Device Report M345060, M317126, various dates, Sorin Biomedical, Inc.

24.) Medical Device Report M344176, received 9/2/92, Sorin Biomedical, Inc.

25.) Medical Device Report M324153, received 9/30/92, Sorin Biomedical, Inc.

26.) Medical Device Report M321079, received 8/13/92, Sorin Biomedical, Inc.

27.) Medical Device Report M285491, received 4/29/92, Sorin Biomedical, Inc.

28.) Medical Device Report M283413, received 4/15/92, Sorin Biomedical, Inc.

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Title of person submitting 510(k): Advanced Regulatory Affairs Coordinator
Name of Company: 3M Health Care
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